



UNITED STATES PATENT AND TRADEMARK OFFICE

ck

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 09/673,617 | 01/25/2001 | Kim Sorensen | 030307/0191 | 2002 |
| 22428 | 7590 | 03/24/2006 | | |
| FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | EXAMINER BURKHART, MICHAEL D | |
| | | | ART UNIT 1633 | PAPER NUMBER |

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,617

Applicant(s)

SORENSEN ET AL.

Examiner

Michael D. Burkhardt

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/13/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43,44,46,48 and 52 is/are allowed.
- 6) ☒ Claim(s) 45, 50, 53, 54 and 55 is/are rejected.
- 7) ☒ Claim(s) 47,49 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt and entry of the amendment dated 12/13/2005 is acknowledged. After entry of the amendment, claims 43-55 are pending.

Claim Objections

Claim 47 is objected to because of the following informalities: "bacteriophase" should be "bacteriophage" in the final line. Appropriate correction is required.

Claim 49 is objected to because of the following informalities: "lysine" should be "lysin" in line 2. Appropriate correction is required.

Claim 51 is objected to because of the following informalities: "abence" in line 8 should be "absence." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45, 50, 53, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 53 recites bacterium containing one of the vectors pFG100 or pFG200 (lines 2-3), and which comprise a recombinant vector (limitations (A)-(C)). The pFG100 and pFG200 vectors are disclosed as comprising the components listed as (A)-(C) in the claim (for example see Fig. 5). It cannot be determined if the claimed bacteria comprise a single vector (e.g.

Art Unit: 1633

pFG100 or pFG200) or two vectors, each of which has the same functional elements. Therefore, the metes and bounds of the claimed subject matter are unclear.

Claim 45 recites, in part (C), a suppressor that results from "at least one change, preferably two or three changes, of nucleotide in said anticodon." The recited CUA anticodon has already been changed (otherwise it would not be a suppressor gene), so it is unclear if the anticodon is to undergo further changes or not. Therefore, the metes and bounds of the claimed subject matter are unclear.

Claim 50 recites a vector that, in line 7, lacks a gene for antibiotic resistance, but also comprises a gene for nisin (an antibiotic) resistance (line 8). It is unclear how the claimed vector can have both properties, therefore the metes and bounds of the claimed subject matter are unclear.

Claim 55 recites, in part (A), nonsense mutant cells which cannot grow in a particular environment and which carry a *pyr* mutation. It cannot be determined if the nonsense mutation is the *pyr* mutation (as in claim 52), or if they are two separate mutations. Therefore, the metes and bounds of the claimed subject matter are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1633

Claims 45 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Dickely et al (Mol. Micro., 1995). This rejection is maintained for reasons of record (as applied to claims 1-4, 7, 9-14, 16, 17, 22-25, 28-29, 31-33, 36-38, 40 and 42 in the Office Actions of 6/30/2004 and 7/13/2005) and for reasons set forth below.

Response to Arguments

Applicant's arguments filed 12/13/2005 have been fully considered but they are not persuasive. Applicants argue that the new claims have incorporated all the limitations of claims indicated as allowable in the previous Office Action. However, claim 45 is identical in scope with canceled claim 7, previously rejected under this statute as being anticipated by Dickely et al. See the Office Actions of 6/30/2004, 7/13/2005, and page 844, first column, second full ¶ of Dickely et al. Claim 54, which is similar to cancelled claim 34 (not previously rejected on these grounds), is included in the rejection because in the course of producing the pFG1 vector, bacterial transformants containing the vector were isolated by plating and culturing (page 843, first column and page 845, first column), each of which (absent evidence to the contrary) involves more than 10^5 colony forming units per gram. For example, to be visible on a plate, a bacterial colony must be at least 10^7 cfu.

Conclusion

Claims 43, 44, 46, 48, and 52 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

Art Unit: 1633

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1633

A handwritten signature in black ink that reads "Scott D. Pribe". The signature is written in a cursive, flowing style.

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER